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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/454,223	12/09/1999	RICHARD S. KORNBLUTH	SD9-003-1	3505

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/454,223

Applicant(s)

KORNBLUTH, RICHARD S.

Examiner

Jegatheesan Seharaseyon, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 16-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.130, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.130, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.130. Applicant's submission filed on 6/30/2006 has been entered. An action on the RCE follows.

Status of Application, Amendments and/or Claims

2. The amendments and remarks of 20 December 2005 and 30 June 2006 have been entered in full.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 7, 16, 17, 20, 21, 23 and 25 are amended. Claim 8 has been cancelled. Claims 1-6 and 9-15 remain withdrawn. Therefore, claims 7 and 16-28 are under consideration in the instant application.

5. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 112 (New matter)

6. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

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time the application was filed, had possession of the claimed invention. This is a new matter rejection. The specification provides no written description support for "in reading frame", "the first about 100 to 300 N-terminus residues", "a second polypeptide comprising C-terminus residues", "wherein the amino acids comprising" and "of the first polypeptide are replaced by the last about 10 to 250 amino acids comprising an extracellular domain of the second polypeptide".

The specification does not provide basis for the amendment throughout the specification, specifically Tables I, II and page 11, line 1.

Claim Rejections - 35 USC § 112

7. Claims 7 and 16-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7a. Claim 7 is rejected as being vague and indefinite for the recitation of "in reading frame". In reading frame in the art refers to DNA sequence not to peptide sequences. However, claim is drawn to fusion polypeptide. Therefore, it is unclear if Applicant is fusing the polypeptide or polynucleotides. This rejection maybe obviated by Applicant deleting the phrase "in reading frame". Claims 16-28 are rejected insofar as they depend from claim 7.

7b. Claims 7 is rejected as being vague and indefinite for the recitation of "multimeric polypeptide of trimer units". It is not clear if Applicant is considering a protein complex or fusion polypeptide, as the latter recitation seems to indicate. Claims 16-28 are rejected insofar as they depend from claim 7.

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7c.Claim 7 recites the limitation "wherein the amino acids comprising a carbohydrate recognition domain (CRD)" in "line 9". There is insufficient antecedent basis for this limitation in the claim. Claims 16-28 are rejected insofar as they depend from claim 7.

7d.Claim 7 recites the limitation "100 to 250 amino acids comprising an extracellular domain" in lines 10 and 11. There is insufficient antecedent basis for this limitation in the claim. Claims 16-28 are rejected insofar as they depend from claim 7.

7e. Claims 18 and 19 are rejected as being vague and indefinite for the recitation of "trimer unit is a homotrimer" or "trimer unit is a heterotrimer". The assertions are inconsistent; it appears based on the recitation of claim 7 the multimeric polypeptide of the instant invention is either a homotrimer or heterotrimer. It is suggested that Applicant to overcome this rejection modify the claim language to recite "wherein the multimeric polypeptide is a homotrimer or heterotrimer". Alternatively, the base claim could be directed to the individual subunit, with dependent claims to the dimers, trimer complex.

7f. Claims 20 is rejected as being vague and indefinite for the recitation of "amino acid sequence is surfactant protein D". Sequence is not the protein. This rejection maybe obviated by Applicant rewriting the claim to read " collectin family protein is the surfactant protein D".

7g.Claim 27 recites the limitation "wherein sites of proteolytic degradation are removed from the multimeric polypeptide" in line 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

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7h. Claims 28 is rejected as being vague and indefinite for the recitation of "multimer is a dimer". Claim 28 depends from claim 7, which describes the multimer to be a trimer. Therefore, it is unclear if the multimer of the instant invention is a trimer or dimer.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

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later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8a. Claims 7 and 16-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoppe et al. (U.S. Patent No. 6, 190, 886) in view of Maraskovsky et al. (U.S. Patent No. 6, 017, 527).

The claims are drawn to multimeric polypeptide collectin and TNFSF.

Hoppe et al. teaches the formation of collectin fusion proteins. It teaches that fusion protein comprise the neck region of the collectin protein (column 1, lines 43-46). It also teaches that the neck region of collectin protein is able to mediate inter-chain recognition and trimerization (column 1, lines 43-46). The reference further teaches that the results make available simple means of trimerising polypeptides of choice. The reference also discloses homotrimer and heterotrimers (column 4, lines 65-67). It also discloses one or more heterologous amino acids joined to the neck region of the collectin protein (column 1, lines 55-59 and column 2). However, this study does not disclose the fusion of collectin polypeptide to TNFSF polypeptide.

Maraskovsky et al. (U.S. Patent No. 6, 017, 527) disclose CD40L fusion proteins. The reference teaches that CD40L polypeptides may be created by fusion of the C terminal of soluble CD40L to the Fc region of IgG1 (column 7, lines 31-33). The reference also teaches CD40 polypeptides may exist as oligomers, such as dimers or trimers (column 7, lines 24-25). It would have been *prima facie* obvious at the time of the invention to modify the fusion protein

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disclosed in Hoppe et al. with the teachings of Maraskovsky et al. to comprise the c-terminal region of CD40L, a TNFSF protein. One of ordinary skill in the art would have been motivated to modify the fusion protein disclosed in Hoppe et al. with the teachings of Maraskovsky et al. (containing CD40L) because the reference teaches that CD40 polypeptides form oligomers such as dimers and trimers (column 7, lines 24-25). Further, there is reasonable expectation of success because Hoppe et al. to generate fusion protein comprising the collectin because Hoppe et al. disclose that fusing collectin at the c-terminal with heterologous polypeptides (ligands) allows for the binding of the ligands to receptors (column 8, line 42-43). Therefore, the instant invention is *prima facie* obvious over Hoppe et al. (U.S. Patent No. 6, 190, 886) in view of Maraskovsky et al. (U.S. Patent No. 6, 017, 527).

Conclusion

9. No claims are allowable.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

(i). Stone et al. (2006) discloses fusion protein comprising collectin (SP-D) and TNFSF (CD40L).

(ii) Tamada et al. (2006) is a review disclosing immunotherapy using TNFSF molecules.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose

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telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
Art UNIT 1647,
October, 23 2006.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud